· IN T	HE UNITED STATES PATENT AND TRADEMARK OFFICE	
THE COMMISSIONER Co-Washington, D.C. 20231	OF PATENTS AND TRADEMARKS	11/05/0/ 11/05/0/
In re the application of: For: Filed: Application No.: Art Unit:	Yung-fu Chang EHRLICHIA CANIS GENES AND VACCINES November 2, 2001	
Attorney Docket No.:	CRF-2322 CIP	
	INFORMATION DISCLOSURE STATEMENT	٠
List of	Sections Forming Part of This Information Disclosure Statement	
The following sections are	being submitted for this information Disclosure Statement	
1. [X] Preliminary Statem	ients	•
2. [X] FORM PTO - 1449	9 (Modified)	
3. Statement As To In	nformation Material To Examination Not Found in Patents or Publications	
	ior Application In Which Listed Information Was Already Cited and For Which ted Or Need Be Submitted	No
5. Cumulative patents	or Publications	
6. [X] Copies of Listed Int	formation Items Accompanying This Statement	
7. Concise Explanation	n of Non-English Language Listed Information Items.	
8. Translation(s) of No	on-English Language Documents	
9. Certification under l	MPEP 609(e)	
10. [X] Identification of Pe	erson(s) Making This Information Disclosure Statement	

[X] Express Mail No: EL 637188 CERTIFICATE OF MAILING

Date: 11/2/0/

I hereby certify that this correspondence is being deposited with the United States Postal Service, return receipt requested in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on this date.

### Section 1. Preliminary statements

Applicant submits herewith patents, publications or other information of which he is aware, which he believes may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 CFR 1.56(g)), an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

### Section 2. Form PTO - 1449 (Modified) (SEE ATTACHMENT)

- \*EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw a line through citation if not in conformance or not considered. Include a copy of this form with the next communication to applicant.
- Section 3. Statement As To Information Material For Examination Not Found in Patents or Publications (Information not listed in PTO 1449)
- Section 4. Identification of Prior Application in Which Listed Information Was Already Cited and For Which No Copies Are Submitted Or Need Be Submitted

09/358.322 07/21/99 (ItemsAA-AC; AD-BN; BO-BS and BT-BW already submitten

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Section 5. Cumulative Patents or Publications
Item(s) are cumulative of the following patents or publication listed on Form PTO 1449 (modified):
n accordance with 37 CFR 1.98(c) a copy of is being submitted with this information disclosure statement.
Section 6. Copies of Listed Information Items Accompanying This Statement
Legible copies of all items listed accompany this information statement.
Exception(s) to above:
☐ Items in prior application from which an earlier filing date is claimed for this application as identified in Section 4. ☐ Cumulative patents or publications identified in Section 5.
Section 7. Concise Explanation of Non-English Language Listed Information Items
Section 8. Translation(s) of Non-English Language Documents
Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions of those patents, publications or information considered to be material:  No English language translations of the foreign language patents, publications or information or

parts thereof are readily available, except for those listed above.

sub	The following foreign language documents submitted are believed to be the equivalent or stantial equivalent of the English language documents identified below, which are also submitted ewith.
Section 9.	Certification under Rule 1.97
The un	ndersigned hereby certifies that:
a. 7	This Statement is being filed after the latest of (1) three months after the filing date of a national application; (2) three months after the date of entry of the national stage as set forth in w 1.491 in an international application; (3) the mailing date of a first Office action on the merits.
<b>b</b> . 7	The fee set forth in §1.17(p)
	☐ Is being paid with this Information Disclosure Statement
	Is not due because:  (1) Each item of information contained in the information disclosure statement was cited in a communication from a foreign-patent office in a counterpart foreign application not more than three months prior to the filing of the statement, or  (2) No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the statement.
Section 10	D. IDENTIFICATION OF PERSON(S) MAKING THIS INFORMATION DISCLOSURE STATEMENT
The person	n making this statement is
(a)	the inventor(s) who signs below
	[X] the attorney who signs below on the basis of:  the information supplied by the inventor(s)  an individual associated with the filing and prosecution of this application (37 CFR 1.56(c)).  [X] the information in the attorney's file
BROWN & 400 M&T Ithaca, New Voice: (6 e-mail: bpr	Par A. Michaels, Registration No. 34,390  Red MICHAELS, PC  Bank Building, 118 N. Tioga Street  W York 14850-4343  07) 256-2000 Fax: (607) 256-3628  m@bpmlegal.com  number: 020808

# Section 2. Form PTO - 1449 (Modified) (ATTACHMENT)

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FORM PTO-1449 U.S. DEPT. OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. CRF-2322	SERIAL NO.
	APPLICANT CHANG	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE .7/21/99	GROUP 1632

### U.S. PATENT DOCUMENTS

Exam Initial	·	DOCUMENT NUMBER	DATE	PATENTEE	CLASS	SUB	FILING DATE IF APPROPR
25	AA	5,192,679	3/9/93	Dawson, J.E. et al.	435	243	
1	AB	5,401,656	3/28/95	Dawson, J.E.	435	243	17 .
	AC	5,413,931	5/9/95	Dawson, J.E.	435	252.1	7
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# FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Exam Initial		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB	TRANSLATION YES   NO
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### OTHER PRIOR ART

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	AD	Althchul, S.F. et al, 1990, "Basic local aligment search tool", J. Mol. Biol. 215: 403-410.
	AE	Betsou, F. et al, 1995, "Cloning and sequence of the Bordetella bronchiseptica adenylate cyclase-hemolysin- encoding gene: comparison with the Bordetella pertussis gene", Gene 162: 165-166.
	AF	Breitschwerdt, E.B. et al, 1998, "Doxycycline hyclate treatment of experimental canine Ehrlichiosis followed by challenge inoculation with two Ehrlichia canis strains", Antimicrobial Agents and Chemotherapy 42(2): 362-368.
	AG	Chang, Y.F. et al, 1987, "Identification and characterization of the <i>Pasteurella haemolytica</i> Leukotoxin", Infect. Immun. 55: 2348-2354.
	AH	Chang, Y. F. et al, 1989a, "Secretion of the <i>Pasteurella</i> leukotoxin by E. coli", FEMS Microbiology Let. 60: 169-174.
	AI	Chang, Y. F. et al, 1989b, "Cloning and Characterization of a hemolysin gene from Actinobacillus (Haemophilus) pleuropneumoniae", DNA 8(9): 635-647.
	AJ	Chang, Y. F.et al, 1993a, "Molecular characterization of a leukotoxin gene from a Pasteurella haemolytica-like organism, encoding a new member of RTX family", Infect. Immun. 61:2089-2095.
	AK	Chang, Y.F. et al, 1993b, "Molecular analysis of the Actinobacillus pleuropneumoniae RTX toxin-III gene cluster", DNA and Cell Biol. 12: 351-362.
	AL	Chang, Y.F. et al, 1993c, "Expression and secretion of outer surface protein (OspA) of Borrelia burgdorferi from E. coli", FEMS Microbiol. Lett. 109: 297-302.
	AM	Chang, Y.F. et al, 1995, "Recombinant OspA protects dogs against infection and disease caused by Borrelia burgdorferi", Infect. Immun. 63:3543-3549.
	AN	Dawson et al. 1991, "Serologic diagnosis of human Ehrlichiosis using two Ehrlichia canis isolates", Journal of Infectious Diseases 163: 564-567.
	AO	Degen, et al, 1986, "The human tissue plasminogen activator gene", Journal of Biological Chemistry 261(15): 6972-6985.

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LAB	Donnelly et al. 1003 "Targeted delivery of penti	ide epitopes to class I major histocompatibility molecules by a		
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	Dunley of al. 1002 "Call mediated immune recr	conses of adults to vaccination, challenge with Rickettsia		
AQ	Dumler et al, 1992, Cell-inculated infinition resp	(2), 105.115		
	rickettsii, or both", Am. J. Trop. Med. Hyg 46(	ectors pEF <sub>2</sub> BOS, pcDNA1 and pcDNA3 result in improved		
AR	Goldman, L.A. et al, 1990, Modifications of v	ectors per-503, periodic and periodic result in improved		
	convenience and expression", BioTechniques 21	1: 1013-1013.		
AS	Guermonprez, P.D. et al, 1999, "Direct delivery	of the Bordetella pertussis adenylate cyclase toxin to the MHC		
	class I antigen presentation pathway", J. Immun	101. 162. 1910-1916.		
AT	Gupta, R.K. and Siber, G.R., 1995, "Adjuvants	for human vaccines- current status, problems and future		
	prospects", Vaccine 13(14): 1263-1276.			
AU	Harrus, et al., 1998, "Amplification of Ehrlichi	al/DNA from dogs 34 months after infection with Ehrlichia		
	canis", Journal of Clinical Microbiology 36(1):	<i>7</i> 3-76.		
AV	Keysary et al, 1996, "The first isolation, in vitro	propagation, and genetic characterization of Ehrlichia canis in		
	Israel", Veterinary Parasitology 62: 331-340/			
AW	Klinman, D. M. et al, 1997, "CpG motifs as in	nmune adjuvants", Vaccine. 17:19-25.		
AX	Launois et al. 1994, "T-cell epitope mapping of	f the major secreted myobacterial antigen Ag85A in tuberculosis		
	and leprosy". Infection and Immunity 62(9): 36	579-3687.		
AY	Lee B and Horwitz, M.A. 1999, "T-cell epito	pe mapping of the three most abundant extracellular proteins of		
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AZ	Nyika A et al 1998 "A DNA vaccine protect:	s mice against the rickettsial agent Cowdria ruminantium",		
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DA	District of al 1992 "Analyses of Ehrlichia can	is and a canine granulocytic Ehrlichia infection", Journal of		
BA	Clinical Microbiology 30(1): 143-148.	is and a carrie grandicoydo Danisana antonion , tomana or		
	Robinson, H.L, 1997, "Nucleic/acid vaccines:	on overview" Veccine 15/8): 785-787		
BB	Robinson, H.L., 1997, Nucleic acid vaccines:	an overview, vaccine 15(6). 765-767.		
BC	Sebo, P, C. et al, 1995, "Cell-invasive activity	y of epitope-tagged adenylate cyclase of Bordetella pertussis		
	allows in vitro presentation of a foreign epitope	to CD8+ cytotoxic T cells", Infect. Immun. 63:3851-3857.		
BD	Stewart, G.S. et al, 1986, "pHG165: A pBR322 copy number derivation of pUC8 for cloning and expression",			
	Plasmid 15:172-186.	C.1 Louis Ebeliahia ganas areading high		
BE	Storey, J.R. et al 1998, Molecular cloning and	sequencing of three granulocytic Ehrlichia genes encoding high		
	molecular-weight immunoreactive proteins", Inf	fection and immunity 60(4): 1336-1363.		
BF	Uetsuki et al, 1989, Isolation and characterizat	tion of the human chromosomal gene for polypeptide chain		
	elongation factor-10(", Journal of Biological Ch	nemistry 264(10): 5791-5798.		
. BG	Wen et al, 1997, Comparison of nested PCR w	with immunofluorescent-antibody assay for detection of Ehrlichia		
	canis infection in dogs treated with doxycycline'	", Journal of Clinical Microbiology 35(7): 1852-1855.		
BH	White, A. P. et al, 1999, "High efficiency gene	e replacement in Salmonella enteritidis: chimeric fimbrins		
	containing a T-cell epitope from Leishmania ma	jor", Vaccine 17: 2150-2161.		
BI	Yuk, M.H. et al, 1998, "The BygAS virulence	control system regulates type III secretion in Bordetella		
	bronchiseptica", Mol. Microbiol. 28:945-959.			
BJ	Cotter, P/A, and Miller, J.F., 1994, "BvgAS-m	nediated signal transduction: analysis of phase-locked regulator		
	mutants of Bordetella bronchiseptica in a rabbit	model", Infect. Immun. 62: 3381-3390.		
BK	Favolle et al. 1996. "In vivo induction of CTL	responses by recombinant adenylate cyclase of Bordetella		
	pertussis carrying viral CD8+ T cell epitopes",	J. Immun. 156:4697-4706.		
1 BL	Evnan et al. 1993. DNA Vaccines: protective in	nrnunizations by parenteral, mucosal and gene-gun		
l BL	inoculations" Proc. Natl Acad. Sci USA 90:11478-11482.			
BM	Gigh W et al 1993 "Identification of protein of	coding regions by database similarity", Natural Genetics 13: 26		
PIM	272.			
Dat	Charat at 1 1004 "Identification of the antigeni	ic constituents of Ehrlichia chaffeensis", Am. J. Tropic. Med.		
BN		to communicate of continents of the state of		
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# U.S. PATENT DOCUMENTS

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	во	WO 98 42743 A	10/1/98	Europe			
	BP	WO 98 16554 A	4/23/98	US			
	BQ	WO 99 X3720 A	3/25/99	US			
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Exam Initial		Author, Title, Date, Pertinent Pages, Etc
	BR	Waghela, S.D. et al, 1991, "A cloned DNA probe identified Cowdria ruminantium in Amblyomma variegatum ticks", Jnl of Clinical Microbiology, vol. 29, n. 11, pgs 2571-2577
	BS	EMBL, Heidelberg, Germany; I40883, August 16, 1996, Abstract
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FORM PTO-1449 U.S. DEPT. OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. CRF-2322	SERIAL NO. 09/358,322
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Exam Initial		Author, Title, Date, Pertinent Pages, Etc					
	BT	Frelberg, C. et al, 1997, Molecular basis of symbiosis between <i>Rhizobum</i> and legumes", Nature, Vol 387, pp 384-401					
	BU	Springer, A. et al, 1996, Characterization and Nucleotide Sequence of pqqE and pqqF in Methlobacterium extorguens AM1, Journal of Bacteriology: pp 2154-2157.					
	BV	DATABASE EMPRO1, Yamane, K. et al, 1997, "The 25 degrees region of the Bacillus subtilis chromosome determination of the sequence of a 146kb segment and identification of 113 genes", 1 page.					
	BW	DATABASE EMPRO1, Andersson, S.G. et al, 1998, "The genome of sequence of Rickettsia prowazekii and the origin of mitochondria", 1 page.					
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# Section 2. Form PTO - 1449 (Modified) (ATTACHMENT)

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FORM PTO-1449 U.S. DEPT. OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. CRF-2322 CIP	SERIAL NO.
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### **U.S. PATENT DOCUMENTS**

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	CA	6,043,085	03/28/00	Yu, et al	435		<u> </u>
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### OTHER PRIOR ART

Exam		Author, Title, Date, Pertinent Pages, Etc				
Initial						
	СВ	Appel, M.J. et al, 1993, Experimental Lyme Disease in Dogs Produces Arthritis and Persistent Infection; Jnl of				
$-)\omega$		Infectious Diseases, 167, pp 651-654.				
70	CC	Chang, Y. et al, 1998; Detection of human granulocytic ehrlichiosis agent and Borrelia burgdorferi in ticks by				
<u> </u>		polymerase chain reaction, J. Vet. Diagn Invest.; 10, pp 56-59.				
20	CD .	Chang, Y. et al, 1998, Experimental infection of the human granulocytic ehrlichiosis agent in horses; Veterinary				
70		Para.; 78, ppp. 137-145.				
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./১	CF	Altschul, S. et al; Results of Blast; http://www.ncbi.nlm.nih.gov/blast/Blast.cgi, 9-				
٩٥٠		14-01, 40 pages.				
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		Joe Waster 1/18/05				